Science Ethics Rules Leave Room for Scandals, Critics Fear

By PAUL BASKEN

McDaniels General Store, near Rough River Lake and about a half-hour drive off the freeway that cuts through central Kentucky, offers kerosene, live bait, and made-to-order deli sandwiches.

For Melinda M. Zaragoza, it also offers peace of mind.

Too many times during her nine-year path to a doctorate in microbiology at the University of California at Davis, Ms. Zaragoza says, she saw what she thought were instances of colleagues' falsifying test data to win research grants or impress superiors. One of the worst episodes was in 2004, she claims, when her department chairwoman ordered her to ignore test data that might have contradicted the chairwoman's industry-supported study of HIV drugs. "If it didn't say what we wanted it to say, we either got a different test or ignored it," Ms. Zaragoza says.

She filed some complaints with her university, but university-led reviews repeatedly cleared the chairwoman. So last year, Ms. Zaragoza quit her scientific career and literally headed for the hills. "People here," she says, while serving customers at her counter, "tend to be a little more honest."

Although no wrongdoing was found on the Davis campus, Ms. Zaragoza's whistle-blowing now is being joined by a powerful chorus. Officials of the National Institutes of Health are considering new ethics regulations. Many individual states are also toughening rules. And several dozen universities, pressed by Congress and embarrassed by high-profile ethical lapses among their faculty members — including professors at Harvard and Emory Universities — have recently outlined new conflict-of-interest policies, mostly focused on increased disclosure of financial ties.

There is a lot at stake. Federal research grants provide universities with about $30-billion annually. And in medical research, falsified results can lead to bad treatments for deadly diseases.

But simple disclosure may not go far enough. Few institutions have hard and fast rules defining what is and is not a conflict, according to a new *Chronicle* survey. (See detailed results on Page A8.) Some experts who have been studying fraud reporting for years say the problems will continue as long as the NIH, Congress, and others in the federal government let universities police themselves, particularly when their own substantial financial stakes in the system are a great incentive to turn a blind eye.

How blind? University scientists witness 2,300 instances of misconduct each year, but universities report only about 24 of them to the government's Office of Research Integrity, wrote Sandra L. Titus, the office's director of intramural research, and her colleagues in a report published last year in the journal *Nature.* The estimate of misconduct cases was extrapolated from survey responses from more than 2,200 researchers nationwide.

"There's this mind-set that disclosure is the magic bullet," said Patricia M. Tereskerz, an associate professor of ethics and policy in health care at the University of Virginia who has studied conflict-of-interest practices. "But it's not. Disclosure will not correct the moral wrong."

Universities as Judge and Jury

Ms. Zaragoza described to university officials a series of incidents in which she believed her professor, Satya Dandekar, an AIDS researcher who heads the department of medical microbiology and immunology at UC-Davis, improperly overruled challenges to her findings.

One incident involved a professor who attributed test data to animal blood samples that, Ms. Zaragoza said, could not be found in the records of their federally financed facility, the California National Primate Research Center. Ms. Dandekar refused to exclude the use of the data, Ms. Zaragoza said.

And during studies of tenofovir, an anti-HIV drug made by Gilead Sciences, Ms. Zaragoza said, Ms. Dandekar ordered her to throw out test data from one group of primates that contradicted results from a previous set of animals suggesting a need for the drug. The second group of animals had a medical condition that would have made their data ineligible for the study, but Ms. Zaragoza said Ms. Dandekar was unaware of that problem at the time she ordered the data excluded.

A university spokesman, Andy H. Fell, said the reviews that exonerated Ms. Dandekar were conducted fairly and in accordance with federal requirements. He also said he would not make Ms. Dandekar available to answer questions about the incidents.

If a review had found misconduct, the university could have been forced to pay back an NIH grant and the professor might have been ineligible for future federal money. But the exculpation was unequivocal, Mr. Fell said.

"That is the system," Mr. Fell said. "That's the system here, it's the system at Harvard, it's the system at Iowa State, it's the system anywhere in the country." Changing that system is "not really a question for us," he said. "Congress can write new laws and set up new guidelines if they choose to do so."

Blame on Congress

Congress, however, doesn't appear to be considering a radical new approach. Sen. Charles E. Grassley, Republican of Iowa, is the leading activist on Capitol Hill on reforming conflicts in medical research. But Mr. Grassley is largely emphasizing financial disclosure of industry ties. His chief policy prescription is the Physician Payments Sunshine Act, a bill he drafted with Sen. Herb Kohl, Democrat of Wisconsin, that would require physicians who receive $100 or more from pharmaceutical companies and device manufacturers to publicly disclose all such payments and gifts.

Colleges are largely happy to accept that level of federal regulation. The Association of American Universities and the Association of American Medical Colleges have both endorsed the Grassley-Kohl bill, as did 57 percent of the university research administrators responding to the *Chronicle* survey.

Yet that survey also showed that few institutions actually limit income that a scientist can receive from a company. This attitude, Ms. Tereskerz said, has been encouraged by Congress itself. With the Bayh-Dole Act of 1980, Congress pushed universities to commercialize discoveries stemming from federally financed research, she said. More than a third of lead authors are now estimated to hold personal financial stakes in their research, and more than two-thirds of universities hold equity in outside businesses that sponsor their research, Ms. Tereskerz said.

She has suggested changes that include creating a government-supported clearinghouse to match researchers with a drug or technology to be evaluated, thereby keeping the scientists away from the company and avoiding a direct financial relationship between the two.

'Chummy' NIH Approach

Others believe the problem would be more directly attacked by detecting and punishing fraud rather than trying to publicize or constrain payments to researchers.

Researchers conducting federally financed research are entrusted with taxpayer money and human lives, and those found guilty of fraud "should be held personally liable, and they should be charged with criminal conduct," Brian P. Hanley, a graduate student in microbiology at UC-Davis who assisted Ms. Zaragoza in her complaints against Ms. Dandekar, told the NIH in a written comment as part of its evaluation of new rules.

That's not what typically happens. More common are cases such as that involving Judith M. Thomas and Juan R. Contreras, two University of Alabama at Birmingham scientists who were temporarily barred from receiving federal grant money earlier this month after they were found by the Office of Research Integrity to have falsified animal-study results. The two researchers had been using rhesus monkeys to study the effectiveness of drugs to prevent transplanted organ rejection. Among other things, the scientists removed only one of two kidneys from each animal, thereby exaggerating the apparent benefit of the drugs, the office said.

Even as he promotes financial disclosure, Senator Grassley says the NIH could toughen its approach, including revoking the grants of any university scientist who fails to report a financial conflict of interest. "If NIH was doing its job," he said, "we wouldn't have these problems."

The problem is the "kind of a chummy relationship between NIH bureaucrats and these universities around the country," he said. But Senator Grassley said he did not want to go immediately beyond a disclosure requirement, "because so many times I've seen transparency accomplish the goal."

Universities have argued emphatically against any federal interference in their right to police research, even in cases involving federal money. Most faculty members care strongly enough about their institutional reputation to root out any cheaters in their midst, said Robert P. Lowman, associate vice chancellor for research at the University of North Carolina at Chapel Hill. Using outside agencies or scientists to oversee a university's research would be costly, "and I don't know that it will be better, enough better, to be worth the extra time and expense that's involved," Mr. Lowman said.

Just a Few Bad Actors

No system can fully eliminate all "bad actors," said Robert M. Berdahl, president of the Association of American Universities.

"There are a lot of checks and balances that prevent the fudging and shading of results," said Mr. Berdahl, who served as chancellor of the University of California at Berkeley from 1997 to 2004. "I don't think there's evidence of a broad systemic problem."

A faculty-led group, the Association of Clinical Researchers and Educators, is gathering for the first time this week in Boston to promote the idea that university collaborations with industry provide an overall benefit to medical research. Its organizer, Thomas P. Stossel, a professor of medicine at Harvard, said he agrees with those who want the emphasis more on fighting actual fraud than on monitoring financial ties.

It is not clear, however, that either universities or individual professors know the size of the problem. Some of the most prominent examples cited by Senator Grassley of researchers' collecting payments from companies whose products they study or promote — such as Joseph Biederman of Harvard University, Charles B. Nemeroff of Emory University, and Thomas A. Zdeblick of the University of Wisconsin at Madison — were revealed primarily by newspaper investigations rather than by universities or government.

Another concern, says Norman C. Ellstrand, a professor of genetics at the University of California at Riverside, is that "bad actors" may drive out good scientists. He ran the lab where Ms. Zaragoza worked for two years after leaving Davis, finishing her doctorate there before leaving for Kentucky.

Mr. Ellstrand said Ms. Zaragoza showed "consistently superior performance in essentially everything she did," and he is troubled that alleged bad behavior by colleagues has cost the research world a promising scientist. "There's no question there are sharks out there," Mr. Ellstrand said, "and people suffer by them."

MANY COLLEGES DO NOT DRAW BRIGHT LINES FOR RESEARCH CONFLICTS

Colleges have been reluctant to set limits on outside compensation that could create conflicts of interest, *The Chronicle* has found in a survey of university research administrators. We heard from a total of 132 institutions.

Do you support a proposal in the U.S. Senate (S 301) requiring corporations to post on the Internet all payments to clinical researchers by name, in order to increase disclosure and transparency about financial conflicts of interest?

	All respondents	Major research universities
Yes	57%	57%
No	19%	16%
No opinion	24%	27%

Has your institution required any of its researchers to turn down income and/or equity from a corporation that is currently financing his or her research?

	All respondents	Major research universities
Yes	28%	48%
No	72%	52%

Has your institution set a maximum, across-the-board limit for income and/or equity that researchers may receive or hold from a corporation that is currently financing their research?

	All respondents	Major research universities
Yes	22%	24%
No	78%	76%

NOTE: A "major research institution" means one that received $100-million or more in federal research grants in the 2007 fiscal year. Institutions in that elite group received the large majority of all money for academic science. Percentages are rounded.

A CHRONICLE SURVEY OF UNIVERSITY RESEARCH ADMINISTRATORS

Now that President Obama and the National Institutes of Health have announced plans to expand federal financing for research on human embryonic stem cells, does your institution plan to expand the research staff and lab space devoted to such studies?

	All institutions	Major research institutions*
By a large amount	3%	6%
Somewhat	43%	67%
Not at all	54%	27%

Does your institution currently conduct any such research?

	All institutions	Major research institutions*
Yes	40%	63%

No	60%	38%

Does your institution plan to conduct research on human stem cells derived from blastocysts created through SCNT (somatic cell nuclear transfer), using nonfederal financing?

	All institutions	Major research institutions*
Yes	12%	23%
Maybe, after further study of the ethical, legal, and social implications	44%	56%
No	44%	21%

If you had to pick one, what should be the National Institutes of Health's top priority in spending the extra research money that it will receive from the federal economic-stimulus legislation enacted this year?

	All institutions	Major research institutions*
Increase the number of research awards	44%	42%
Help younger scientists land independent research grants and start careers	37%	32%
Increase financing for revolutionary, outside-of-the-box research proposals	12%	14%
Increase the amount of the average research award	4%	8%
Increase the duration of the average research award	2%	2%
Other	1%	2%

Does your institution conduct research on your campus using laboratory animals?

	All institutions	Major research institutions*
Yes	97%	100%
No	3%	0%

In the past two years, have opponents of animal research taken any of the following actions against researchers at your institution who work with laboratory animals? (check all that apply)

	All institutions	Major research institutions*
A researcher received harassing or threatening phone calls, e-mail, or letters	23%	37%
Contact or other personal details about a researcher were posted online	14%	24%
Demonstrations at a researcher's home or work	11%	28%
Break-in or vandalism at a researcher's home	4%	10%
Break-in or vandalism at a researcher's laboratory or office	3%	6%

Because of activists who oppose animal research, by how much, if any, has your institution reduced the volume of lab-animal research (measured by total money spent or number of studies) during the past two years?

0%	92%	86%
More than 0% and up to 25%	2%	2%
More than 25% and less than 100%	0%	0%
My institution ended all such research	0%	0%
My institution increased this research (for whatever	6%	12%

reason)

In the past two years, by how much has your institution increased total spending for security (e.g., alarms, cameras, security officers) to protect researchers working with laboratory animals?

	All institutions	Major research institutions*
Zero	40%	20%
More than zero but less than $1-million	56%	74%
$1-million or more but less than $2-million	2%	2%
$2-million or more	2%	4%

Approximately how much did your institution spend last year on research-administration costs that would have been reimbursed by the federal government but for its 26-percent cap on administrative costs on research grants?

	All institutions	Major research institutions*
Less than $1-million	39%	13%
$1-million or more but less than $3-million	27%	26%
$3-million or more but less than $6-million	17%	26%
$6-million or more but less than $10-million	6%	11%
$10-million or more	11%	24%

By approximately how much has your institution's unreimbursed spending above the federal government's cap increased compared with five years ago?

	All institutions	Major research institutions*
0%	12%	7%
More than 0% but less than 50%	64%	56%
50% or more but less than 100%	17%	27%
100% or more but less than 200%	6%	7%
200% or more	2%	4%

What percentage of researchers hired last year by your institution's medical school were required to obtain 100 percent of their total salary and expenses through "soft money" (financing from noninstitutional sources) as a condition of their hiring?

	All institutions	Major research institutions*
Zero	28%	26%
1% to 33%	30%	50%
34% to 66%	1%	2%
67% to 100%	2%	4%
No medical school	40%	17%

What is the average total start-up package for a young researcher at your institution?

	All institutions	Major research institutions*
Less than $500,000	67%	32%
$500,000 or more but less than $1-million	23%	43%
$1-million or more but less than $1.5-million	9%	21%
$1.5-million or more but less than $2-million	1%	2%
$2-million or more	1%	2%

Compared with a few years ago, approximately how many additional hours per week are you

working now as a research administrator?

	All institutions	Major research institutions*
Zero	14%	10%
5 hours	27%	28%
10 hours	33%	30%
15 or more hours	27%	33%

* A "major research institution" is defined here as one that received $100-million or more in federal research grants in the 2007 fiscal year. Institutions in that elite group received the large majority of all money for academic science.

NOTE: Percentages are rounded and so may not add to 100 percent.